Field Name	Field Description
Prior Authorization Group Description	**Complement Inhibitors**
Drugs	Empaveli (pegcetacoplan), Fabhalta (iptacopan), Izervay (avacincaptad pegol injection), Soliris (eculizumab), Syfovre (pegcetacoplan injection), Ultomiris (ravulizumab), Voydeya (danicopan), PiaSky (crovalimab-akkz), BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the criteria will be approved as follows: Initial Requests • 3 months: eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 6 months: Fabhalta (iptacopan). PiaSky (crovalimab-akkz) • 12 months: Syfovre (pegcetacoplan), Izervay (avacincaptad pegol) Reauthorization • 6 months: eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 12 months: Syfovre (pegcetacoplan), Fabhalta (iptacopan), PiaSky (crovalimab-akkz) No Reauthorization Izervay (avacincaptad pegol)
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, body weight, and concomitant medical conditions; **AND** • For Fabhalta (iptacopan), eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), PiaSky (crovalimab-akkz), and Voydeya (danicopan) o Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. • For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.

Revision/Review Date **7**4/2025	**Paroxysmal Nocturnal Hemoglobinuria (PNH):**
	• Documentation of diagnosis by high sensitivity flow cytometry
	• **Presence of 1 or more of the following PNH-related signs or symptoms:**
	  ○ **Fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia, history of a major adverse vascular event (including thrombosis), dysphagia, erectile dysfunction, or history of pRBC transfusion due to PNH.**
	• ~~Hemoglobin (Hgb) < 10.5 g/dL for Empaveli (pegcetacoplan), or Hgb < 10 g/dL for Fabhalta (iptacopan)~~
	• **Adults: For Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Fabhalta (iptacopan), or PiaSky (crovalimab-akkz) patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.**For Voydeya (danicopan):
	  ○ Member has been receiving eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) therapy for at least 6 months
	  ○ Member has clinically evident extravascular hemolysis [defined as anemia (Hgb ≤9.5 gram/deciliter) with absolute reticulocyte count ≥120 x 10^9/liter] despite treatment with eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)
	  ○ Voydeya (danicopan) will be used as add-on therapy to eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)
	
	Generalized Myasthenia Gravis (gMG):
	• Refer to the "Myasthenia Gravis Agents" policy
	
	Neuromyelitis Optica Spectrum Disorder (NMOSD)
	• Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy
	
	IgA Nephropathy:
	• **Refer to the "IgA Nephropathy Agents" policy**
	
	Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)
	• Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR**
	• Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient

	Geographic Atrophy (GA): • If the request is for Syfovre (pegcetacoplan injection), member must be ≥ 60 years of age • If the request is for Izervay (avacincaptad pegol injection), member must be ≥ 50 years of age • Diagnosis of GA secondary to age-related macular degeneration (AMD) • Absence of choroidal neovascularization (CNV) in treated eye • Best-corrected visual acuity (BCVA) of 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS) • GA lesion size ≥ 2.5 and ≤ 17.5 mm^2 with at least 1 lesion ≥ 1.25 mm^2 **Complement 3 Glomerulopathy (C3G):** • **Diagnosis of C3G as confirmed by renal biopsy** • **Patient's serum C3 level is reduced (defined as less than 0.85 x lower limit of the central laboratory normal range)** • **Patient's urine protein to creatinine ratio (UPCR) is ≥ 1.0 g/g** • **Patient has an eGFR ≥ 30 mL/min/1.73 m^2** • **Patient has been taking maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 90 days, or a medical reason is provided why this is inappropriate** • **Patient has a trial and therapy failure of mycophenolate and glucocorticoids, or a medical reason is provided why this is inappropriate.** • **Patient does not have recurrent C3G post kidney transplant** **Re-Authorization:** • Re-authorization may be considered for all agents included in these criteria with the exception of Izervay (avacincaptad pegol injection), which is only indicated for a 12 month duration • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lesions, etc.); **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, body weight, and concomitant medical condition; **AND** • If the request is for aHUS/Complement Mediated HUS o Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies **Medical Director/clinical reviewer must override criteria when, in**

	his/her professional judgement, the requested item is medically necessary.